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Method and Arrangement for Respiratory Support of a Patient as well as Airway Prosthesis and Catheter

The invention concerns a method and an arrangement for respiratory support of the patient, as well as an airway prosthesis and a catheter for use herein.

To allow the body to take up oxygen and release carbon dioxide, both components of the respiratory bronchial system must function. The lung as a gas exchanging organ and the respiratory pump as a ventilation organ which transports air into the lung and back out again. The correct function of the respiratory pump requires the respiration centre in the brain, central and peripheral nerves, the bony thorax and the respiratory musculature, as well as clear, stable airways.

In certain illnesses, there is a long-term overuse or exhaustion of the respiratory pump. A typical illness is lung emphysema with flat diaphragm, and inability to contract. In

lung emphysema, the airways are usually extremely limp and collapsed. Due to the flattened, overstretched diaphragm, the patient cannot inhale deeply enough. Due to the collapsed airways, the patient is also unable to exhale sufficiently. This leads to insufficient respiration with oxygen undersupply and increased carbon dioxide levels in the bloodstream, which is also known as ventilatory insufficiency.

Treatment of inhalatory weakness is often done with a respirator. The so-called home respiration is artificial respiration to support or completely unburden the respiratory pump.

Respiration can take place non-invasively via a tube and a nose or mouth mask which the patient can put on and take off by himself as required. However, this restricts free breathing and the patient's ability to speak. Furthermore, a blocked tracheal cannula can be inserted into the trachea. This also means that the patient can no longer speak.

In invasive respiration, this is usually carried out via a tracheostoma. This is a surgically created opening in the trachea. Via the opening, a finger-thick catheter with a blocking balloon is inserted into the trachea and connected to a respirator. This enables sufficiently deep respiration, but hinders the patient in speaking. Aside from respiration, there is transtracheal oxygen administration via thinner catheters. Corresponding suggestions can be found in US-A-5,181,509 or US-A-5,279,288. In this manner, the patient receives high-dosed oxygen in a continuous stream with a fixedly adjusted frequency. The oxygen is regulated manually via a regulator. It is not possible to adapt to the patient's natural respiration process. Respiration is not deepened. The catheter end which is introduced into the airway may also lead to irritation and local trauma to the surrounding tissues by striking the trachea due to the movement of respiration, or the surrounding tissues are dried out by the jet stream.

So-called "Montgomery-T tubes" which are placed within the trachea are also known. Through these, the patient can receive oxygen via the segment of the T which is directed to the outside. Furthermore, the patient can suction off his secretions himself when required. The patient can breathe freely and speak if the front segment is closed. However, artificial respiration is not possible through the "Montgomery-T tube", since the air which is introduced escapes upwards into the mouth and/or pharynx.

Based on the state of the art, the invention therefore has the task of providing a more efficient process for respiratory support for a patient, and to create an arrangement for this purpose which can also be carried by the patient and is safe to use. Furthermore, the invention aims at an airway prosthesis and a catheter which enables respiratory support that is synchronized with the patient's spontaneous respiration without negatively affecting the ability to speak.

The solution of the method section of the task consists of a method which includes the measures in Patent Claim 1.

According to this, the patient's spontaneous respiration is recorded by sensors, and an additional amount of oxygen is administered at the end of a respiratory process. This can take place in the form of an oxygen burst via a jet catheter from an oxygen reservoir. Herein, there is synchronization of respiratory support with the patient's natural respiration. Respiratory depth which is reduced due to overwork or exhaustion of the respiratory pump is thus compensated. Due to the additional oxygen quantity, respiration is kept at sufficient levels. Oxygen undersupply and increased carbon dioxide in the blood are thereby avoided.

For practical purposes, the additional oxygen quantities have a volume between 25 ml and 150 ml, as shown in Patent Claim 2.

If desired, the patient's exhalation process can also be slowed by a counter-flow as needed. This is always recommended when the patient's airways are collapsible, that is,

they collapse during respiration, which can extremely hinder the exhalation process. This is prevented by the measure of patent claim 3 in that a counter-flow is applied during exhalation, keeping the airways open and preventing their collapse.

A representational solution to the problem on which the invention is founded is an arrangement in accordance with the characteristics of patent claim 4. This intends an oxygen pump which can be connected to an oxygen source, as well as an airway prosthesis which, if applicable, can be connected via a catheter with the further use of a supply tube. The outflow end of the catheter forces the oxygen flow into a jet character. This may, for instance, be accomplished by a reduction of the cross-section. In principle, the end of the catheter may also be equipped with a jet nozzle. Furthermore, the invention intends sensors to record the patient's spontaneous respiration. These sensors are linked with a control unit for activation of the oxygen pump. The airway prosthesis possesses a tubular support body with a connector for the catheter. The support body and the integrated catheter are dimensioned so that the patient can breathe and speak freely, without restriction. The main respiration takes place through the larger inner lumen of the airway prosthesis. Spontaneous respiration, coughing and speaking are not hindered. Furthermore, the support body includes at least two sensors which are part of the arrangement.

The airway prosthesis is implanted in the airway of the patient. A small airway incision is made to provide access for the catheter to the outside. The catheter can be led directly into the support body with one end via the connector. It is also possible to connect the catheter to the connector externally via a coupling mechanism.

The sensors serve to record the patient's spontaneous respiration. Various respiration sensors, such as respiration flow sensors or pressure sensors, can be used. Thermistors are particularly advantageous. These are semi-conductor components with temperature-dependent resistance. The temperature dependency of the resistance forces is used to record the

inhalation and exhalation processes, since the exhaled air in the lung is naturally warmer within the airway than the inhaled air.

In accordance with the characteristics of patent claim 5, a sensor is applied to the internal wall of the supporting body. The other sensor is arranged on the external wall of the support body or embedded within the support body itself.

A bridge circuit is provided for compensation of the recorded measurement value differences between the internal and external sensors. This double arrangement can be used to equalize environmental influences, such as temperature variations etc.

In accordance with the characteristics of patent claim 6, the catheter end which is located within the support body is largely positioned parallel to its longitudinal axis and provided with a jet nozzle at its end. This may be a separate nozzle. However, the jet nozzle may also be designed in the form of a reduction in cross-section at the end of the catheter. In this manner, the air or oxygen flow which is introduced via the catheter can be aimed in the direction of the lungs, and this can be accomplished with a laminar flow. The oxygen is prevented from escaping into the mouth or pharyngeal space. The support body which receives the catheter end or end piece prevents dehydration of the surrounding tissues. Trauma to the airway and/or surrounding tissues, e.g. through movements of the catheter end, is furthermore avoided.

The oxygen pump is functionally structured as a piston pump. The use of a cylinder with a double-action piston or a movable membrane is particularly preferable. Such an oxygen pump excels due to its compact construction. Furthermore, reliable adjustment of the supplied oxygen quantity is possible in supporting both the exhalation process and the inhalation process. Since the maximum quantity of air per jet lift is limited by the cylinder size, overinflation of the lung with consequential baro trauma is also prevented.

Within the framework of the arrangement as per the invention, it is possible to use two catheters, wherein one jet catheter is used to support

the inhalation process, and the other catheter is used for precisely slowing the exhalation process. A catheter can also be constructed with a double lumen, as intended in patent claim 8. The double-lumen catheter provides separate channels for the administration of oxygen in the inhalation process and in the exhalation process.

The security of the arrangement is increased through the provision of additional respiration sensors. These, too, are sensors which record the patient's spontaneous respiration. These may, for instance, be affixed to the patient's chest so that spontaneous respiration can be monitored through a thorax impedance measurement. Sound or flow measurement at the patient's mouth or nose is also a possibility. Inhalation or exhalation support is provided by equalizing the recorded signals from the airway and the further respiration sensors in a control unit and sending corresponding signals to the oxygen pump. The additional respiration sensors guarantee redundant construction and contribute to the security of the arrangement.

In accordance with patent claim 10, self-reliant protection is desired for the airway prosthesis as per the invention. This possesses a tubular support body with a connector for a catheter, with at least two sensors which are arranged on the support body. The airway prosthesis excels in its ability to allow measurement of the patient's respiration. This permits synchronization of external respiratory support with the patient's own respiration.

A sensor is advantageously mounted on the internal wall of the support body (patent claim 11). Thermistors are regarded as particularly suitable within the framework of the invention. By linking the thermistors via a bridge circuit, it is possible to compensate for temperature differences between the internal and external thermistors. This double arrangement of the sensors in the bridge circuit compensates for environmental influences, such as temperature variations, or also differences which may be caused by secretions coming into contact with the internal sensor, thereby producing localized cooling or warming.

It is furthermore advantageous in accordance with patent claim 12 if the catheter end is placed within the support body so that it is parallel to the longitudinal axis of the support body. This results in directional provision of the oxygen flows in the direction of the bronchial tract, with laminar flow conditions.

Furthermore, independent protection is desired for a catheter as per patent claim 13, whose outflowing end includes at least one sensor. It is functional to provide at least two sensors in this location in order to be able to carry out the compensation of measurement values within a bridge circuit.

Such a catheter can be introduced into a support body from the outside. such a support body may, for instance, consist of the well-known "Montgomery-T-Stent". The catheter is introduced from the externally accessible segment of the T segment so that respiration can be supported via the catheter.

According to the characteristics of patent claim 14, the end of the catheter possesses a jet nozzle. As already described above, this can, for instance, be provided by a reduction in the cross-section of the end. However, it may also consist of a separate jet nozzle.

The end of the catheter is preferably bent as intended in patent claim 15. In this manner, the end which is introduced into the airway or support body is naturally oriented into the direction of the bronchial tract, parallel to the longitudinal axis of the support body.

The invention is described in further detail by the attached drawings. The following are shown:

Figure 1 The upper body of a patient who is wearing a respiratory support arrangement as per the invention.

Figure 2 A diagram showing the respiratory flow of an emphysema patient, with and without respiratory support.

Figure 3 A technically simplified representation of an airway prosthesis as per the invention.

Figure 4 A further embodiment of an airway prosthesis.

Figure 5 Also, in the schema, an oxygen pump belonging into the arrangement as per the invention, depicting control of the air flow, as well as a control unit.

Figure 6 The end section of a catheter as per the invention, and

Figure 7 the catheter placed into a support body as in figure 6.

Figure 1 uses P to indicate a patient suffering from lung emphysema, with overwork and exhaustion of the respiratory pump. This renders the patient unable to inhale deeply enough. The exhalation process is furthermore obstructed by limp and collapsing airways.

Such a respiration process with inhalation (inspiratorial flow) and exhalation (expiratorial flow) is shown in figure 2 in the left half of the image. The inhalation curve is identified as E1, while the exhalation curve is identified with A1.

To support and unburden the respiratory pump, the patient's spontaneous respiration is recorded by sensors, and an additional quantity of oxygen is administered to the lungs at the end of an inhalation process. This respiration flow is further clarified in figure 2 in the right half of the image. The additional quantity of oxygen increases the respiration volume during inhalation as shown in curve E2 by the differential volume which is darkened in on the upper curve, and identified as E3. The additional oxygen quantity may possess a volume between 25 ml and 150 ml.

The patient's exhalation process is furthermore slowed by a counter-flow. This causes the respiratory flow during exhalation to shift as shown in the curve which is identified as A2. This resistance, which specifically counteracts the exhalation flow, prevents airway collapse during exhalation. This process enlarges the exhalation volume by the volume which is also darkened in, and identified as A3.

This process consequently prevents insufficient respiration with oxygen undersupply and increased carbon dioxide levels in the bloodstream. The patient P is significantly more stressable and mobile, as well as feeling less or no respiratory distress.

The arrangement which is intended to provide respiratory support to the patient P includes an oxygen pump 1 which can be connected to an oxygen source (see figure 5) and an airway prosthesis 2, 3 (see figures 3 and 4). In accordance with figure 1, the oxygen pump 1 is part of a compact mobile respiration unit 4. The oxygen pump 1 and the airway prostheses 2 and 3 are connected via a catheter 5.

As figures 3 and 4 show, each airway prosthesis 2 and 3, respectively, possesses a tubular support body 6 with a connector 7 for the catheter 5. Two sensors 8, 9 are assigned to the support body 6 in the form of thermistors for the purpose of recording the patient's spontaneous respiration. Herein, a sensor 8 is fastened to the internal wall 10 of the support body 6, while the other sensor 9 is located at the outside wall 11 of the support body 6. The sensors 8, 9 are connected with a control unit 12 for activating the oxygen pump 2. The control unit 12 is schematically shown in figure 5 with its entries and exits. As already mentioned, the sensors 8, 9 are thermistors, that is, temperature dependent resistors. These are linked in a bridge circuit within the arrangement, so that the compensation of measurement values between the inner sensor 8 and the outer sensor 9 takes place in response to environmental influences.

It is furthermore shown in figure 1 that further respiration sensors 13, 14 are intended. These are likewise sensors for recording the spontaneous respiration of the patient P. Equalization of the measurement values recorded by the sensors 8 and 9, as well as 13 and 14, provide a precise depiction of the respiratory process of the patient P. Security against erroneous measurements or failure of one of the sensors 8, 9 as well as 13, 14 is furthermore improved.

In the airway prosthesis 2 as per figure 3, the jet catheter 5 can be introduced into the support body 6 via the connector 7. The end of the jet catheter 15 which is located within the support body 6

is guided / redirected parallel to the longitudinal axis L of the support body. The data conduits of the sensors 8, 9 for the control unit 12 are identified as 16 and 17. These run within the catheter 5. At the outflow end 15, the jet catheter 5 is designed as a jet nozzle 25. This can be accomplished by a reduction of the catheter cross-section. This increases the speed of the oxygen flow at the exit of the catheter 5, directing it into the direction of the bronchial tract. The diameter of the support body 6 is dimensioned with a lumen which is sufficiently large so that the patient P can breathe and speak freely even with the integrated catheter 5.

In the airway prosthesis 3 as per figure 4, a separate coupling 18 is provided at the connector 7 to connect the catheter 5 to the airway prosthesis 3. In this case, within the support body 6 and parallel to the longitudinal axis L, a fixed length segment 19 is intended as a catheter end, wherein the oxygen flow is directed into the direction of the bronchial tract via a jet nozzle 26.

The oxygen pump 1 is schematically shown in figure 5. It involves a cylinder pump with a double-action piston 20 which is arranged within a cylinder 27. The arrangement possesses a total of four valves V1 to V4. Oxygen is supplied out of an external oxygen reservoir via the connector 21. The switching conditions of the valves V1 to V4, as well as the incoming and outgoing supply lines, are identified by the letters a to g.

In respiratory support, the function of the oxygen pump 1 within the arrangement is as follows:

When the valve V1 from c to a are open (b to c closed) and the valve V2 from b to e is open (e to d closed), the piston 20 at the image level moves to the left, and oxygen flows through the outlet 22 and the jet catheter 5 to the patient P. The additional quantity of oxygen E3 is administered during the inhalation process of the patient P.

When the valve V1 from b to c (c to a closed) is open, and the valve V2 from e to d is open (b to e closed), the piston 20 at

the image level moves to the right, and oxygen flows out in the direction of the valve V3. The valve V3 is connected to the outside air via an outlet 23. If the valve V3 from d to g is open, the oxygen flows without an expiration resistor: This means that the exhalation process is not slowed by a counter-flow.

If the valve V3 from d to g is closed, and is open from d to f, the oxygen flows in the direction via the supply line 24 to the outlet 22 and the catheter 5 to be administered to the patient P during the exhalation process, as well as slowing the respiratory flow. The counter-flow prevents airway collapse and keeps the airways open. This enables deeper exhalation.

In the supply line 24 of the arrangement, the valve V4 is also switched, allowing variable adjustment of the flow-through (f to a). This may preferably consist of a proportional valve with pulse width modulation.

Figure 6 shows a catheter 28 with a long, flexible tube 29 and an outflow end 31 which is angled through the use of a bent segment 30. The end includes two sensors 32, 33 to record the spontaneous respiration of a patient P. The sensors 32, 33 preferably consist of thermistors. The representation of data cables has been omitted for the sake of simplicity. These run through the catheter 28 or the catheter wall. 34 identifies a stop.

It is furthermore recognizably shown that the end 31 of the catheter 28 is provided with a jet nozzle 35. Within the jet nozzle 35, the flow cross-section is reduced relative to the cross-section of the catheter, so that the exit speed of the supplied oxygen is increased.

The catheter 28 may be introduced into a support body 36, as shown in figure 7. The support body 35 is located within the airway of a patient P. The connection to the outside is provided via a connector 37.

The support body 36 may consist of a customary "Montgomery-T-Stent".

List of reference symbols

1 - Oxygen pump

2 - Airway prosthesis

3 - Airway prosthesis 4

Respirator

5 - -Catheter

6 - Support body 7

Connector

8 - Sensor

9 - Sensor

10 Internal wall, front 6 11

External wall, front 6 12

Control unit

13 - Respiration sensor

.14 - Respiration sensor

15- End, front 5

16- Data cable

17- Data cable

18- Coupling

19- Length segment

20- Piston

21 - Connector

22 - Outlet

23- Outlet 24

– supply line

25- Jet nozzle

26- Jet nozzle

27- Cylinder

28- Catheter

29- Tube

30 - Bend

31 - End, front 28

32- Sensor 33 -

Sensor

34 - Stop
35- Jet nozzle
36- Support body
37 - Connector
P- Patient
E1 – Inhalation curve
E2 - Inhalation curve
E3 - Volume A1 –
Exhalation curve A2 –
Exhalation curve A3 -
Volume

V1 - Valve
V2- Valve
V3- Valve
V4- Valve

L- Longitudinal axis, front 5

a - line
b - line
c- line
d - line
e - line
f- line
g - line